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The effectiveness of an education and information programme to prevent relapse in people suffering from bipolar disorder

Submission date
18/12/2018

Recruitment status
No longer recruiting

Registration date
07/02/2019

Overall study status
Completed

Last Edited
22/03/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Bipolar Disorder (BD) is a chronic disorder and is the sixth leading cause of disability among physical and psychological disorders worldwide. Although medication is needed, the role of psychosocial factors both in the onset and in the course of BD has become increasingly evident and has led to the development of several psychosocial approaches as adjunctive treatment to pharmacological therapies. Among several psychological treatments, psychoeducation has been shown to be effective in helping people with BD recognize early signs and adopt behavioural measures to prevent full-blown episodes, which are frequently associated with high morbidity and more hospital admissions.

Although to date the benefits of group psychoeducation in the management of BD are well known, the evidence that the positive effects of psychoeducation persist over time is still weak and there are few studies about effectiveness of psychoeducation provided in ordinary mental health services.

In a previous study we evaluated the effectiveness of psychoeducation at 1-year follow-up; one group attended psychoeducation and one group was on a waiting list. The results showed that the number of patients hospitalized during the 1-year follow-up, the mean number of hospitalizations per patient, and the mean number of hospitalization days were significantly lower for psychoeducation patients.

In this study we want to evaluate the outcomes of psychoeducation at 4-year follow-up, in order to assess the long-term effectiveness of psychoeducation over time. Furthermore, we wanted to see if there are variables that can predict who will better respond to psychoeducation. In fact, there are still two key questions that need to be addressed: how to predict who will most benefit from psychoeducation, and consequently to which patients to propose it.

Who can participate?
Patients suffering from Bipolar Disorder.

What does the study involve?
One Department of Mental Health, that could not implement psychoeducation for organizational problems, provided patients for the control group and these patients received Treatment As Usual (TAU); the other DMH implemented the psychoeducation and provided patients for the experimental group. Patients in the experimental group received, in addition to TAU, group psychoeducation performed according to Colom and Vieta's model; it consisted of 21 sessions of 90 minutes (Colom and Vieta, 2006). These sessions aimed to improve four main issues: illness awareness, treatment adherence, early detection of prodromal symptoms and lifestyle regularity. The psychoeducation was delivered in groups of 8-12 participants, conducted by two clinical psychologists, who had previously attended a training psychoeducation course directly held by Francesc Colom.

What are the possible benefits and risks of participating?
Benefits: patients participating in psychoeducation will be able to prevent relapse, recognizing symptoms early and adopting a regular and protective lifestyle. This will lead to a reduction in BD recurrences, which have a very negative impact on patients' lives.

Risks: in some patients, the participation in psychoeducation could increase their level of anxiety about Bipolar Disorders.

Where is the study run from?
This study runs from the experience of the Bipolar Disorder Program in Barcelona, an excellence center for the treatment of people suffering from Bipolar Disorder. Their clinical experience and the strong scientific evidence of their studies have driven us in this study.

When is the study starting and how long is it expected to run for?
The overall project started in June 2009 and recruitment for this pragmatic trial started in January 2010.

Who is funding the study?
This project was funded by the Lombardy Region, "Progetti Innovativi per la Salute Mentale" (TR15).

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TR15-417

Study information

Scientific Title
Effectiveness of group psychoeducation for bipolar disorder in ordinary mental health services

Acronym
PSYCHOBIPOEFFE

Study objectives
Patients attending psychoeducation will have fewer recurrences than patients who will not participate in the psychoeducation program

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRCCS St. John of God Clinical Research Centre, 27/01/2010, ref. 96/2009/P

Study design
Interverntional, non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Bipolar disorder

Interventions
The study involved two Dept of Mental Health (DMHs): DMH-1 implemented the psychoeducation and provided patients for the experimental group; DMH-2, which for organizational reasons was unable to implement the psychoeducational programme, provided patients for the control group. Both DMH are located in neighboring areas.

The study involved two groups of outpatients: patients in the experimental group received treatment as usual (TAU), consisting of one monthly visit with the treating psychiatrist and pharmacological treatment specific for BD, and additional psychoeducation according to Colom and Vieta's model (Colom and Vieta, 2006), consisting of 21 sessions of 90 minutes. These sessions aimed to improve four main issues: illness awareness, treatment adherence, early detection of prodromal symptoms and lifestyle regularity. The psychoeducation was delivered in groups of 8-12 participants, conducted by two clinical psychologists, who had previously attended a training psychoeducation course directly held by Francesc Colom. The attendance to psychoeducation was considered complete until to five missing sessions.

Patients in the control group received only TAU. During the 1- and 4-year follow-up all participants continued to receive TAU; the experimental group did not receive booster sessions of psychoeducation.

Intervention Type
Behavioural

Primary outcome measure
Any episode of BD relapse with hospitalization was measured using the official Lombardy Region's electronic Psychiatric Case Register.

Secondary outcome measures
All data concerning hospitalizations were retrieved from the official Lombardy Region's electronic Psychiatric Case Register:
1. Number of subjects hospitalized
2. Number of hospitalizations
3. Number of days of hospitalization

Overall study start date
23/06/2009

Completion date
31/12/2014

Eligibility

Key inclusion criteria

1. A lifetime diagnosis of BD type I or II
2. Being euthymic for at least 3 months
3. Sufficient information about illness course during ≥18 months prior to start of psychoeducation (collected from the medical record and from the psychiatrist)
4. Willingness to continue current medication
5. Written informed consent to participate in group psychoeducation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. DSM-IV Axis I comorbidity
2. Mental retardation (IQ <70)
3. Current substance use
4. Organic brain damage
5. Deafness
6. Patients undergoing any structured form of psychological treatment

Date of first enrolment
01/01/2010

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Italy

Study participating centre
IRCCS St. John of God Clinical Research Centre
Via Pilastroni 4
Brescia
Italy
25100

Study participating centre
Department of Mental Health of Brescia
Piazzale Spedali Civili 1
Brescia
Italy
25100

Study participating centre
Piazza Donatori di Sangue 1
Dept of Mental Health of Desenzano del Garda
Leno (Brescia)
Italy
25024

Sponsor information

Organisation
Regione Lombardia

Sponsor details
Piazza Città di Lombardia 1
Milan
Italy
20124

Sponsor type
Government

Website
http://www.regione.lombardia.it

Funder(s)

Funder type
Government

Funder Name
Programmi innovativi in salute mentale di area territoriale, Direzione Generale Sanità, Regione Lombardia

Results and Publications

Publication and dissemination plan
The trialists now intend to publish the results of the 4-year follow-up.

Intention to publish date
01/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Valentina Candini (vcandini@fatebenefratelli.eu)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2013		Yes	No
Results article		26/11/2019	22/03/2023	Yes	No